Exhibit 13

12/17/2010

INSTRUCTIONS FOR USE FOR:

SEPTAL OCCLUDER

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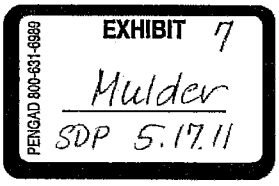
English

FINAL APPROVED



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INSTRUCTIONS FOR USE FOR:

GORE® HELEX Septal Occluder

NOTICE FOR USE WITHIN THE UNITED STATES
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION

The GORE® HELEX Septal Occluder consists of an implantable endoprosthesis and a catheter delivery system.
The occluder is comprised of a nickel-titanium (Nitinol) wire frame covered with expanded polytetrafluoroethylene (ePTFE). The ePTFE is treated with a hydrophilic coating to facilitate echocardiographic imaging of the occluder during implantation. When fully deployed, the occluder assumes a double disc configuration that bridges the septal defect to prevent shunting of blood between the right and left atria (Figures 1a, b). The delivery system consists of three distal co-axial components transitioning to a parallel component arrangement at the proximal Y-arm hub: a 10 Fr Green Delivery Catheter, a Gray Control Catheter and a Tan Mandrel (Figures 1a, 2). The proximal end of the Gray Control Catheter exits the Y-arm hub and is terminated by a Red Retrieval Cord Cap. The proximal end of the Tan Mandrel exits the side port of the Y-arm hub and is terminated by a Clear Luer. The Gray Control Catheter is equipped with a retrieval cord to reposition or retrieve the occluder (Figure 2). A Guidewire Slot is incorporated into the distal end of the Green Delivery Catheter.

FIGURE 1: GORE® HELEX Septal Occluder

FIGURE 1a: Left Atrial View

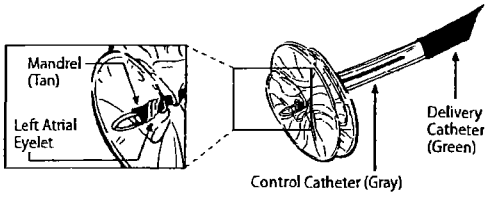


FIGURE 1b: Right Atrial View

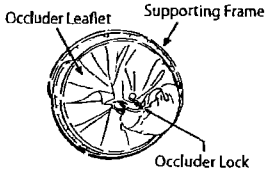
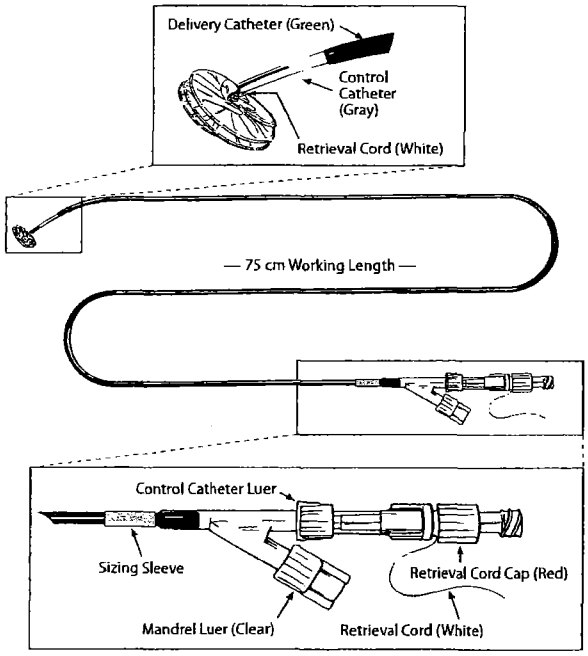


FIGURE 2: GORE® HELEX Septal Occluder Delivery System



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INDICATIONS / INTENDED USE

The GORE® HELEX Septal Occluder is a permanently implanted prosthesis indicated for the percutaneous, transcatheter closure of *ostium secundum* atrial septal defects (ASDs).

CONTRAINDICATIONS

The GORE® HELEX Septal Occluder is contraindicated for use in patients:

- With extensive congenital cardiac anomalies that can only be adequately repaired by cardiac surgery
- Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin, or warfarin
- With anatomy where the GORE® HELEX Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins
- With active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement
- Whose vasculature is inadequate to accommodate one of the GORE® HELEX Septal Occluder Recommended Introducer Sheaths (Table 11)
- With known intracardiac thrombi

WARNINGS

- The GORE® HELEX Septal Occluder is not recommended for defects larger than 18 mm.
- The GORE® HELEX Septal Occluder is not recommended for patients with a septal thickness of greater than 8 mm in the area of the occluder placement.
- The GORE® HELEX Septal Occluder has not been studied in patients known to have multiple defects requiring placement of more than one device.
- The GORE® HELEX Septal Occluder is not recommended for, and has not been studied in, patients with other anatomical types of ASDs that are eccentrically located on the septum (examples include *sinus venosus* ASD and *ostium primum* ASD), or fenestrated Fontan.
- The GORE® HELEX Septal Occluder is not recommended for, and has not been studied in, patients with significant atrial septal aneurysm.
- Regarding device deployment:
  - The defect and atrial chamber size should be evaluated by Transesophageal Echocardiography (TEE) or Intracardiac Echo (ICE) with color flow Doppler measurement to confirm that there is adequate space to accommodate the selected occluder size without impinging on adjacent cardiac structures (e.g., A-V valves, ostia of the pulmonary veins, coronary sinus, or other critical features).
  - There must be adequate room in the atrial chambers to allow the right and left atrial discs to lie flat against the septum with disc spacing equal to the septal thickness, and without interference with critical cardiac structures or the free wall of the atria.
  - The defect should be evaluated to ensure there is an adequate rim to retain the device in ≥ 75% of the circumference of the defect.
  - The selected occluder diameter should be at least two times the diameter of the defect (i.e., a 2:1 ratio of device diameter-to-defect diameter). Deploying the occluder in cases where the occluder diameter-to-defect diameter ratio is below 2:1 increases the risk of unsuccessful device placement and device embolization.
  - An occluder that pulls through the defect during disc confirmation may be too small and should be removed and replaced with a larger size.
- Embolized devices must be removed. An embolized device should not be withdrawn through intracardiac structures unless the occluder has been adequately collapsed within a sheath.
- If successful deployment cannot be achieved after two attempts, an alternative treatment for ASD closure should be considered. Consideration should be given to the patient's total exposure to radiation if prolonged or multiple attempts are required for the placement of the GORE® HELEX Septal Occluder.
- The GORE® HELEX Septal Occluder should be used only by physicians trained in its use, and in transcatheter defect closure techniques. The procedure should be performed only at facilities where surgical expertise is available.
- Patients allergic to nickel may suffer an allergic reaction to this device. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.

PRECAUTIONS

Handling

- The GORE® HELEX Septal Occluder is intended for single use only. An unlocked and removed occluder cannot be reused.
- Inspect the package before opening. If seal is broken, contents may not be sterile.
- Inspect the product prior to use in the patient. Do not use if the product has been damaged.
- Do not use after the labeled "use by" (expiration) date.
- Do not resterilize.

Procedural

- Patients should be heparinized sufficiently to maintain an Activated Clotting Time (ACT) greater than 200 seconds throughout the procedure.
- The GORE® HELEX Septal Occluder should be used only in conjunction with appropriate imaging techniques to assess the septal anatomy and to visualize the wire frame. These techniques include multiplanar TEE or ICE, both with color flow Doppler, and fluoroscopy with real-time image magnification.
- Retrieval equipment such as large diameter sheaths, loop snares, and retrieval baskets should be available for emergency or elective removal of the occluder.
- Removal of an occluder should be considered if:
  - The lock fails to capture all three eyelets
  - The occluder will not come to rest in a planar position apposing the septal tissue
  - The selected occluder is too small and allows excessive shunting
  - There is impingement on adjacent cardiac structures

Post-Implant

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician's routine procedures following device implantation.
- Patients should be treated with antiplatelet therapy, such as aspirin or clopridogrel bisulfate, for six months post-implant. During the Pivotal and Continued Access Clinical Trials, 68.4% of device patients received antiplatelet medications and 0.9% received anticoagulants for up to six months post-procedure (refer to Table 9). The decision to continue antiplatelet therapy beyond six months is at the discretion of the physician.

- In patients sensitive to antiplatelet therapy, alternative therapies, such as anticoagulants, should be considered.
- Patients should be advised to avoid strenuous physical activity for a period of at least two weeks after occluder placement.
- Patients should have Transthoracic Echocardiographic (TTE) exams prior to discharge, and at 1, 6, and 12 months after occluder placement to assess defect closure. Attention should additionally be given towards the stability of the device during these assessments, as a lack of device stability may be indicative of wire frame fractures. In instances where device stability is questionable, fluoroscopic examination without contrast is recommended in order to identify and assess wire frame fractures.

ADVERSE EVENTS

Clinical Summary

Three US clinical studies were conducted to evaluate the GORE® HELEX Septal Occluder. These studies were performed with the original delivery system. The product described in this Instructions for Use is the same occluder with a modified delivery system. Please note that the modified delivery system was not evaluated under the original US clinical study.

The GORE® HELEX Septal Occluder was evaluated in a Feasibility Study (two center, single arm), a Pivotal Study (multi-center, non-randomized), and a Continued Access Study (multi-center, single arm, prospective). The Feasibility Study included 51 subjects treated with the device. The Pivotal Study compared the device to surgical closure of *ostium secundum* atrial septal defects. Investigators were required to complete three device training cases. The Pivotal Study included 119 non-training subjects treated with the device and 128 subjects treated with surgical closure. The Continued Access Study included 137 non-training subjects treated with the device as of August 1, 2006, of which 122 subjects completed the 12 month follow-up evaluation. These subjects form the basis of the observed adverse event data reported in the following section. An independent Data Safety Monitoring Board (DSMB) reviewed all reported adverse events to determine device / procedure relationship and event severity (major or minor). An event was considered major if it required reintervention, readmission to the hospital or resulted in permanent damage or deficit. For the GORE® HELEX Septal Occluder studies, reintervention was defined as chronic medical, and acute surgical or interventional cardiology therapies.

Deaths

There was one post-operative death in the surgical control treatment arm of the Pivotal Study. Subject died of complications related to post-pericardiotomy syndrome on Day 10 post-surgery. No deaths have been reported in the device subjects in the feasibility, Pivotal, or Continued Access Studies.

Observed Adverse Events

Major adverse events reported through the 12 month follow-up for the feasibility, Pivotal and Continued Access Studies are presented in Table 1.

TABLE 1: Number of Subjects with Successful Device Delivery by Category of Major Adverse Events

GORE® HELEX Septal Occluder Studies

Events Reported Through 12 Month Follow-up

		Pivotal Study			
	Feasibility Study	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Subjects Evaluable for Safety	**51**	**119**	**128**		**137**
Deaths (Any Cause)	**0**	**0**	**1 (0.8%)**	**-0.8% (-2.4%, 0.8%)**	**0**
Subjects With One or More Major Adverse Events	**2 (3.9%)**	**7 (5.9%)**	**14 (10.9%)**	**-5.1% (-12.1%, 1.9%)**	**3 (2.2%)**
Cardiac	**1 (2.0%)**	**2 (1.7%)**	**10 (7.8%)**	**-6.1% (-11.5%, -0.8%)**	**2 (1.5%)**
Arrhythmia	1 (2.0%)	0	0		0
Bleeding (treatment required)	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Device Embolization (post-procedure)[2]	0	2 (1.7%)	n/a	n/a	2 (1.5%)
Pulmonary Edema	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Post-Pericardiotomy Syndrome	n/a	n/a	8 (6.3%)		n/a
Integument (Skin)	**0**	**1 (0.8%)**	**0**	**0.8% (-0.8%, 2.4%)**	**0**
Allergic Reaction	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Neurologic	**1 (2.0%)**	**2 (1.7%)**	**0**	**1.7% (-0.6%, 3.9%)**	**0**
Migraine (new)	0	2 (1.7%)	0	1.7% (-0.6%, 3.9%)	0
Paresthesia	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Seizure	1 (2.0%)	0	0		0
Pulmonary (Respiratory)	**0**	**0**	**1 (0.8%)**	**-0.8% (-2.4%, 0.8%)**	**0**
Stridor	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Vascular	**0**	**1 (0.8%)**	**1 (0.8%)**	**0.1% (-2.2%, 2.3%)**	**0**
Hemorrhage (treatment or intervention required)	0	1 (0.8%)	1 (0.8%)	0.1% (-2.2%, 2.3%)	0
Wound	**0**	**0**	**2 (1.6%)**	**-1.6% (-3.8%, 0.7%)**	**0**
Hernia	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Scarring or Scar Related	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Device (GORE® HELEX Septal Occluder)	**0**	**3 (2.5%)**	**n/a**	**n/a**	**1 (0.7%)**
Allergic Reaction	0	1 (0.8%)	n/a	n/a	0
Device Size Inappropriate	0	2 (1.7%)	n/a	n/a	0
Device Removal Due to Fracture	0	0	n/a	n/a	1 (0.7%)
Other	**0**	**0**	**1 (0.8%)**	**-0.8% (-2.4%, 0.8%)**	**0**
Anemia	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0

NOTE: Analysis includes all Feasibility subjects, non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006 and evaluated through 12 month follow-up .

n/a - Not applicable

[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

[2] The four embolized devices were removed by transcatheter technique

Minor adverse events reported through the 12 month follow-up for the Feasibility, Pivotal and Continued Access Studies are presented in Table 2.

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TABLE 2: Number of Subjects with Successful Device Delivery by Category of Minor Adverse Events
GORE® HELEX Septal Occluder Studies
Events Reported Through 12 Month Follow-up

		Pivotal Study			
	Feasibility Study	Device Arm	Surgery Arm	Difference (95% CI)[1]	Continued Access Study
Subjects Evaluable for Safety	**51**	**119**	**128**		**137**
Subjects With One or More Minor Adverse Events	**19 (37.3%)**	**34 (28.6%)**	**36 (28.1%)**	**0.4% (-10.9%, 11.8%)**	**46 (33.6%)**
Cardiac	**7 (13.7%)**	**14 (11.8%)**	**26 (20.3%)**	**-8.5% (-17.8%, 0.7%)**	**7 (5.1%)**
Aortic Insufficiency	0	0	0		1 (0.7%)
Arrhythmia	3 (5.9%)	10 (8.4%)	5 (3.9%)	4.5% (-1.5%, 10.5%)	4 (2.9%)
Chest Pain	1 (2.0%)	2 (1.7%)	0	1.7% (-0.6%, 3.9%)	0
Embolus - Air	1 (2.0%)	0	2 (1.6%)	-1.6% (-3.8%, 0.7%)	0
Hemopericardium	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Hypotension	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Palpitations	1 (2.0%)	0	0		1 (0.7%)
Pericardial Effusion	1 (2.0%)	1 (0.8%)	5 (3.9%)	-3.1% (-6.9%, 0.8%)	1 (0.7%)
Pneumopericardium	0	0	3 (2.3%)	-2.3% (-5.1%, 0.4%)	0
Post-Pericardiotomy Syndrome	n/a	n/a	10 (7.8%)		n/a
Syncope	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Vaso-vagal Reaction	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Integument	**0**	**0**	**0**		**1 (0.7%)**
Abrasion	0	0	0		1 (0.7%)
Musculo-Skeletal	**0**	**0**	**0**		**1 (0.7%)**
Chest Pain	0	0	0		1 (0.7%)
Neurologic	**7 (13.7%)**	**8 (6.7%)**	**0**	**6.7% (2.3%, 11.1%)**	**17 (12.4%)**
Dizziness	2 (3.9%)	0	0		0
Headache	4 (7.8%)	5 (4.2%)	0	4.2% (0.7%, 7.7%)	15 (10.9%)
Migraine (new)	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	1 (0.7%)
Migraine (pre-existing)	0	0	0		2 (1.5%)
Paresthesia	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Visual Field Disturbance or Defect	1 (2.0%)	2 (1.7%)	0	1.7% (-0.6%, 3.9%)	0
Pulmonary (Respiratory)	**0**	**1 (0.8%)**	**8 (6.3%)**	**-5.4% (-10.1%, -0.7%)**	**1 (0.7%)**
Atelectasis	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Congestion	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Dyspnea	0	0	0		1 (0.7%)
Pleural Effusion (not requiring drainage)	0	0	3 (2.3%)	-2.3% (-5.1%, 0.4%)	0
Pneumothorax	0	0	4 (3.1%)	-3.1% (-6.3%, 0.0%)	0
Pneumonia	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Renal and Uro-Genital	**0**	**1 (0.8%)**	**0**	**0.8% (-0.8%, 2.4%)**	**0**
Urinary Retention	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Anesthesia	**1 (2.0%)**	**3 (2.5%)**	**1 (0.8%)**	**1.7% (-1.4%, 4.9%)**	**7 (5.1%)**
Abdominal Pain	0	0	0		1 (0.7%)
Bleeding (no treatment required)	0	0	0		1 (0.7%)
Corneal Abrasion	0	0	0		1 (0.7%)
Emesis	0	1 (0.8%)	1 (0.8%)	0.1% (-2.2%, 2.3%)	1 (0.7%)
Nausea	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Nausea with Emesis	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	4 (2.9%)
Paresthesia	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Sore Throat	1 (2.0%)	0	0		0
Drug-Related	**5 (9.8%)**	**6 (5.0%)**	**2 (1.6%)**	**3.5% (-1.0%, 7.9%)**	**7 (5.1%)**
Allergic Response	1 (2.0%)	0	2 (1.6%)	-1.6% (-3.8%, 0.7%)	0
Bruising / Ecchymosis	2 (3.9%)	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	4 (2.9%)
Gastric Irritation	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	0
Nosebleed	1 (2.0%)	4 (3.4%)	0	3.4% (0.2%, 6.5%)	3 (2.2%)
Rectal Bleeding	1 (2.0%)	0	0		0
Wound	**2 (3.9%)**	**1 (0.8%)**	**4 (3.1%)**	**-2.3% (-5.8%, 1.3%)**	**3 (2.2%)**
Access Site Bleeding	0	1 (0.8%)	0	0.8% (-0.8%, 2.4%)	1 (0.7%)
Access Site Pain	1 (2.0%)	0	0		0
Hematoma (not requiring treatment or intervention)	1 (2.0%)	0	0		2 (1.5%)
Scarring or Scar Related	0	0	2 (1.6%)	-1.6% (-3.8%, 0.7%)	0
Suture Related	0	0	1 (0.8%)	-0.8% (-2.4%, 0.8%)	0
Sternal Wire	n/a	n/a	1 (0.8%)		n/a

Delivery System	**2 (3.9%)**	**1 (0.8%)**	**n/a**	**n/a**	**0**
Mandrel Kink	1 (2.0%)	0	n/a	n/a	0
Retrieval Cord Break	1 (2.0%)	0	n/a	n/a	0
Retrieval Cord Detachment	0	1 (0.8%)	n/a	n/a	0
Device (Fracture of Wire Frame)	**3 (5.9%)**	**6 (5.0%)**	**n/a**	**n/a**	**10 (7.3%)**
Non-Investigational Device Related	**0**	**0**	**0**		**1 (0.7%)**
Contrast Reaction	0	0	0		1 (0.7%)
Other	**0**	**0**	**0**		**3 (2.2%)**
Fever	0	0	0		1 (0.7%)
Nosebleed	0	0	0		1 (0.7%)
Other	0	0	0		1 (0.7%)

NOTE: Analysis includes all Feasibility subjects, non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006 and evaluated through 12 month follow-up.
n/a - Not applicable
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

Potential Device or Procedure-Related Adverse Events

Adverse Events associated with the use of the GORE® HELEX Septal Occluder may include, but are not limited to:

- Repeat procedure to the septal defect
- Device embolization
- New arrhythmia requiring treatment
- Intervention for device failure or ineffectiveness
- Access site complications requiring surgery, interventional procedure, transfusion, or prescription medication
- Thrombosis or thromboembolic event resulting in clinical sequelae
- Impingement on, damage to, or perforation of a cardiovascular structure by the device
- Device fracture resulting in clinical sequelae or surgical intervention
- Air embolism
- Myocardial infarction
- Pericardial tamponade
- Cardiac arrest
- Renal failure
- Sepsis
- Significant pleural or pericardial effusion requiring drainage
- Significant bleeding
- Endocarditis
- Headache or migraine
- TIA or stroke
- Death

CLINICAL STUDIES

Three US clinical studies were conducted to evaluate the GORE® HELEX Septal Occluder. These studies were performed with the original delivery system. The product described in this Instructions for Use is the same occluder with a modified delivery system. Please note that the modified delivery system was not evaluated under the original US clinical study.

Feasibility Study

The GORE® HELEX Septal Occluder was evaluated in a single arm, prospective Feasibility Study intended to provide an initial evaluation of the safety and performance of the GORE® HELEX Septal Occluder for closure of *ostium secundum* atrial septal defects (ASDs). Two US sites participated in the study and enrolled 63 subjects. The median subject age was 11 years (range: six months to 65 years) and 65% of the subjects were female. The median estimated defect size was 12 mm (range: 4.5 to 20 mm), in subjects with a delivery attempt (n=59), the median stretched defect size was 18 mm (range 6 to 26 mm).
The GORE® HELEX Septal Occluder was successfully implanted in 86.4% (51/59) of subjects with a delivery attempt. Subjects with a successful device delivery were followed for 12 months. No deaths, device embolizations, thrombus on the device, or erosions requiring surgery were reported through the 12 month follow-up. There were no repeat procedures to the target ASD in the study population.
Of subjects evaluated for 12 month ASD closure by independent echocardiography core laboratory review, 94.6% (35/37) had a successful defect closure (complete occlusion or clinically insignificant leak). Clinically significant leaks were present in two subjects (5.4%) at the 12 month follow-up evaluation. Clinical success, a composite of safety (no major adverse events or repeat procedure) and efficacy (clinical closure at 12 months), was achieved in 89.5% of subjects (34/38) available for evaluation.

TABLE 3: GORE® HELEX Septal Occluder Feasibility Study
Principal Safety and Effectiveness Results

	Feasibility
Technical Success[1]	51 / 59 (86.4%)
Clinical Closure Success[2]	
Pre-discharge	49 / 51 (96.1%)
6 Months	30 / 31 (96.8%)
12 Months	35 / 37 (94.6%)
Principal Safety Measures	
Major Adverse Events 12 Months	2 / 51 (3.9%)
Minor Adverse Events 12 Months	19 / 51 (37.3%)
Survival at 365 Days (K-M)	100%
Composite Clinical Success 12 Months[3]	34 / 38 (89.5%)

[1] Technical Success defined as successful delivery of the device
[2] Clinical Closure Success defined as defect that is either Completely Occluded or Clinically Insignificant Leak. Leak status was evaluated by the investigational sites at pre-discharge and six months and by the echocardiography core laboratory at 12 months
[3] Composite Clinical Success defined as no major adverse event or repeated procedure and clinical closure success at 12 months

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Purpose - Pivotal and Continued Access Studies

The purpose of the Pivotal Study was to evaluate the safety and effectiveness of the GORE® HELEX Septal Occluder for the closure of *ostium secundum* atrial septal defects. The purpose of the Continued Access Study was to evaluate design modifications to the GORE® HELEX Septal Occluder. The design modifications incorporated into the GORE® HELEX Septal Occluder were implemented based on investigator input and feedback given during the Feasibility and Pivotal Trials.

Patient Selection

Pivotal Study

The Pivotal Study enrolled 143 non-training subjects in the device treatment arm and 128 subjects in the surgical control arm at 14 clinical sites within the US. Investigators who did not participate in the Feasibility Study were required to complete three device training cases. Fifty subjects were enrolled as training cases and these subjects were excluded from the primary endpoint analyses.

Enrolled patients had echocardiographic evidence of an *ostium secundum* atrial septal defect and right heart volume overload (or as indicated by a Q_P:Q_S ratio of ≥ 1.5:1 for the device treatment arm). Patients enrolled in the device treatment arm had a defect size of 22 mm or less as measured by balloon sizing and an adequate rim to retain the device present in ≥ 75% of the circumference of the defect. Patients enrolled in the surgical control arm had surgical intervention within 12 months of IRB approval for the study, a minimum body weight of 8 kg at the time of surgery, and a pre-operative, non-anesthesized echocardiogram performed within six months of the ASD surgery date. Exclusion criteria included:

- Patient had concurrent cardiac defect(s) that were associated with potentially significant morbidity or mortality that could elevate morbidity / mortality beyond what is common for ASD or that is expected to require surgical treatment within two years for the device treatment group or five years for the surgical control group.
- Patient had systemic or inherited conditions that would significantly increase patient risk of major morbidity and mortality during the term of the study.
- Patient had an uncontrolled arrhythmia.
- Patient had history of stroke.
- Patient was pregnant or lactating.
- Patient had contraindication to antiplatelet therapy (device treatment arm).
- Patient had a pulmonary artery systolic pressure greater than half the systemic systolic arterial pressure unless the indexed pulmonary artery resistance was < 5 Woods units (device treatment arm).
- Patient had significant atrial septal aneurysm (device treatment arm).
- Patient had multiple defects that would require placement of >1 device (device treatment arm).
- Patient had an atrial septum > 8 mm thick (device treatment arm).
- Patient had an attempted transcatheter septal defect closure device placement within one month of surgery (surgical control arm).
- Patient had significant pulmonary hypertension at the time of surgery (surgical control arm).
- Patient had already completed a routine 12 month post-operative evaluation (surgical control arm).

Continued Access Study

The Continued Access Study enrolled 189 non-training subjects at 13 clinical sites within the US as of August 1, 2006. Investigators who did not participate in the Feasibility and Pivotal Studies were required to complete three device training cases and these cases were excluded from the primary analyses. Enrolled subjects met the same inclusion and exclusion criteria as the Pivotal Study subjects.

Demographics

The median age of the 143 subjects enrolled in the device treatment arm of the Pivotal Study was 6.5 years (range: 1.4 to 72.4 years) and 65.7% of the subjects were female. The median estimated defect size was 10 mm (range: 1.3 to 25 mm) and in subjects with a delivery attempt (n=134), the median stretched defect size was 14 mm (range 5 to 24 mm).

The median age of the 128 subjects enrolled in the surgical control arm of the Pivotal Study was 4.7 years (range: 0.6 to 70.4 years), and 63.3% of the subjects were female. The median estimated defect size was 15 mm (range: 1.5 to 42 mm).

The median age of the 189 non-training subjects enrolled in the Continued Access Study was 5.4 years (range: 0.8 to 58.4 years) and 65.6% of the subjects were female. The median estimated defect size was 10.0 mm (range: 1.7 to 21.0 mm). In subjects with a delivery attempt (n=160), the median stretched defect size was 14.0 mm (range: 4.5 to 22 mm).

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TABLE 4: GORE® HELEX Septal Occluder Studies
Subject Demographics

	Pivotal Study			Continued Access Study
	Device Arm	Surgery Arm	Difference (95% CI)[1]	
Number of Subjects	143	128		189
Gender				
Male	49 (34.3%)	47 (36.7%)	-2.5% (-13.9%, 9.0%)	65 (34.4%)
Female	94 (65.7%)	81 (63.3%)	2.5% (-9.0%, 13.9%)	124 (65.6%)
Subject Ethnicity				
White or Caucasian	95 (66.4%)	84 (65.6%)	0.8% (-10.5%, 12.1%)	131 (69.3%)
Black or African American	15 (10.5%)	9 (7.0%)	3.5% (-3.2%, 10.2%)	13 (6.9%)
Hispanic or Latino	26 (18.2%)	23 (18.0%)	0.2% (-9.0%, 9.4%)	23 (12.2%)
Asian	3 (2.1%)	7 (5.5%)	-3.4% (-8.0%, 1.2%)	7 (3.7%)
Other	3 (2.1%)	3 (2.3%)	-0.2% (-3.8%, 3.3%)	11 (5.8%)
Unknown	1 (0.7%)	2 (1.6%)	-0.9% (-3.4%, 1.7%)	4 (2.1%)
Subject Age (years)				
n	143	128		189
Mean (Std Dev)	12.4 (14.0)	9.2 (12.2)	3.2 (0.1, 6.4)	8.9 (9.6)
Median	6.5	4.7		5.4
Range	(1.4, 72.4)	(0.6, 70.4)		(0.8, 58.4)
Weight (kg)				
n	143	128		189
Mean (Std Dev)	35.6 (26.0)	27.5 (22.4)	8.2 (2.3, 14.0)	29.3 (22.3)
Median	23.0	17.5		19.0
Range	(9.2, 132.5)	(8.3, 135.0)		(6.9, 114.0)
Body Surface Area (BSA)				
n	143	128		189
Mean (Std Dev)	1.08 (0.51)	0.91 (0.46)	0.2 (0.1, 0.3)	0.95 (0.47)
Median	0.89	0.72		0.77
Range	(0.32, 2.61)	(0.38, 2.01)		(0.33, 2.40)
Estimated ASD Size (mm)				
n	141	124		188
Mean (Std Dev)	10.7 (3.8)	15.5 (6.3)	-4.8 (-6.1, -3.6)	10.2 (3.2)
Median	10.0	15.0		10.0
Range	(1.3, 25.0)	(1.5, 42.0)		(1.7, 21.0)

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006.
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

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TABLE 5: GORE® HELEX Septal Occluder Studies
Subject Medical History

	Pivotal Study			Continued Access Study
	Device Arm	Surgery Arm	Difference (95% CI)[1]	
Subjects Enrolled	143	128		189
General Medical History				
Previous Cardiac Surgery	8 (5.6%)	4 (3.1%)	2.5% (-2.4%, 7.3%)	9 (4.8%)
ECG Abnormalities	72 (50.3%)	89 (69.5%)	-19.2% (-30.6%, -7.7%)	109 (57.7%)
Cardiac Arrhythmia(s)	12 (8.4%)	3 (2.3%)	6.0% (0.8%, 11.3%)	7 (3.7%)
Chromosomal Abnormalities	4 (2.8%)	7 (5.5%)	-2.7% (-7.4%, 2.1%)	16 (8.5%)
Emotional or Psychiatric Problems	5 (3.5%)	0 (0.0%)	3.5% (0.5%, 6.5%)	7 (3.7%)
Epilepsy	0 (0.0%)	0 (0.0%)	0.0% (0.0%, 0.0%)	2 (1.1%)
Failure to Thrive	1 (0.7%)	5 (3.9%)	-3.2% (-6.8%, 0.4%)	8 (4.2%)
Migraines	3 (2.1%)	1 (0.8%)	1.3% (-1.5%, 4.1%)	3 (1.6%)
Neurological Deficits / Symptoms	7 (4.9%)	5 (3.9%)	1.0% (-3.9%, 5.9%)	9 (4.8%)
Other (non-ASD) Cardiac Disease	15 (10.5%)	5 (3.9%)	6.6% (0.5%, 12.6%)	22 (11.6%)
Other Vascular Disease	2 (1.4%)	1 (0.8%)	0.6% (-1.8%, 3.1%)	3 (1.6%)
Pre-term Baby	6 (4.2%)	8 (6.3%)	-2.1% (-7.4%, 3.3%)	15 (7.9%)
Respiratory Difficulties	14 (9.8%)	13 (10.2%)	-0.4% (-7.5%, 6.8%)	23 (12.2%)
Hepatitis	0 (0.0%)	0 (0.0%)		0 (0.0%)
Other	29 (20.3%)	43 (33.6%)	-13.3% (-23.8%, -2.8%)	79 (41.8%)
Current Medication				
Anti-arrhythmic	7 (4.9%)	2 (1.6%)	3.3% (-0.8%, 7.5%)	0 (0.0%)
Anti-coagulant	2 (1.4%)	0 (0.0%)	1.4% (-0.5%, 3.3%)	2 (1.1%)
Anti-hypertensive	4 (2.8%)	2 (1.6%)	1.2% (-2.2%, 4.7%)	2 (1.1%)
Anti-platelet	10 (7.0%)	2 (1.6%)	5.4% (0.7%, 10.1%)	18 (9.5%)
Diuretic	5 (3.5%)	5 (3.9%)	-0.4% (-4.9%, 4.1%)	3 (1.6%)
Other	36 (25.2%)	29 (22.7%)	2.5% (-7.6%, 12.7%)	55 (29.1%)

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006.
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

Design

Pivotal Study

The Multicenter Pivotal Study of the GORE® HELEX Septal Occluder was a non-randomized, controlled trial comparing safety and efficacy outcomes of the GORE® HELEX Septal Occluder with traditional (open) surgical repair of atrial septal defects.

The primary study endpoint was clinical success, a composite evaluation of safety and efficacy, which was evaluated at 12 months post-procedure. Clinical success was defined as: 1) A residual defect classified as either completely occluded or clinically insignificant leak as determined by echocardiography core lab assessment; 2) No repeat procedure to the target ASD; and 3) No major device- or procedure-related adverse events. The study was designed to demonstrate that the clinical success rate of the GORE® HELEX Septal Occluder was not inferior to the clinical success rate for surgical closure of ASDs.

Additional safety endpoints included the proportion of subjects experiencing one or more major and minor device-related and / or procedure-related adverse events through 12 months post-procedure. Additional efficacy endpoints included delivery (technical) success, defined as successful deployment and accurate placement of the GORE® HELEX Septal Occluder to the target ASD, and treatment efficacy, defined as the proportion of subjects with a final residual defect assessment of clinically successful closure (completely occluded or clinically insignificant leak).

Continued Access Study

The Continued Access Study was a prospective, single-arm trial intended to evaluate design modifications to the GORE® HELEX Septal Occluder . The design modifications incorporated into the GORE® HELEX Septal Occluder were implemented based on investigator input and feedback given during the Feasibility and Pivotal Trials. The Continued Access Study endpoints were the same as those of the Pivotal Study and were evaluated at 12 months.

Method

Pivotal Study - Device Treatment Arm

For patients enrolled in the device treatment arm of the Pivotal Study, dimensional verification and characterization of the ASD and surrounding cardiac structures were performed per the investigator's standard methods. An initial static measurement of the septal defect was obtained during echocardiographic visualization. A second measurement was taken utilizing a balloon to gently stretch the defect and measure the balloon's waist (narrowest portion of the balloon), and the balloon stretched defect size was used to determine the optimal size of the GORE® HELEX Septal Occluder per IFU recommendations. Fluoroscopic and echocardiographic guidance were used throughout the procedure for placement of, and at the completion of each procedure to assess the status of, the GORE® HELEX Septal Occluder.

There was no requirement for prior therapy or medical management. All subjects were placed on the investigator's choice of antiplatelet therapy for six months following implantation of the GORE® HELEX Septal Occluder, and on prophylactic, post-procedure antibiotic therapy consistent with the investigator's routine procedure.

Follow-up evaluations, which included a physical exam, ECG, and an assessment of the residual defect status by TTE, were performed at hospital discharge, and at 1, 6, and 12 months post-procedure. If the TTE was inconclusive, a TEE or angiography may have been performed. At the six and 12 month follow-up visits, fluoroscopic examinations were performed to assess device integrity.

Pivotal Study - Surgical Control Arm

Investigators identified surgical control subjects at their respective sites who had undergone an open-heart surgical ASD closure within 12 months of IRB approval of the Pivotal Study, and who also met the inclusion / exclusion criteria for the control arm. Open-heart surgical ASD repair was performed per the investigator's standard procedure, and was achieved by suturing the defect edges or by implantation of autologous or synthetic patch materials over the defect.

Subjects were placed on antiplatelet therapy and prophylactic, post-procedure antibiotic therapy at the investigator's discretion and consistent with investigator's standard method.

Follow-up evaluations, which included a physical exam, ECG, and an assessment of the residual defect status by TTE, were performed at hospital discharge and at 12 months. If the TTE was inconclusive, a TEE or angiography may have been performed.

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Continued Access Study
The methodology and follow-up of the Continued Access Study was the same as that of the device treatment arm of the Pivotal Study.

Results

Pivotal Study - Device Treatment Arm
The GORE® HELEX Septal Occluder was successfully implanted in 88.1% (119 / 135) of subjects with a delivery attempt. No deaths, device-related thrombus, perforations, or erosions requiring surgery were reported. Major adverse events were reported in 5.9% of subjects with a successful delivery through the 12 month follow-up. Clinically successful closure (complete occlusion or clinically insignificant leak), as determined by echocardiographic core laboratory review, was achieved in 98.1% of subjects evaluated at 12 months post-procedure. The primary clinical success endpoint was achieved in 91.9% of subjects evaluated.

Pivotal Study - Surgical Control Arm
Major adverse events were reported in 10.9% of control subjects. One death resulting from complications of post-pericardiotomy syndrome was reported. Clinically successful closure, as determined by echocardiographic core laboratory review, was achieved in 100% of subjects evaluated at 12 months post-procedure. Clinical success was achieved in 83.9% of subjects evaluated.

Continued Access Study
The GORE® HELEX Septal Occluder was successfully implanted in 85.6% of subjects with an attempt. No deaths, device-related thrombus, perforations, or erosions requiring surgery were reported. Major adverse events were reported in 2.2% of subjects with a successful delivery who have been evaluated through 12 months. Clinically successful closure, as determined by echocardiographic core laboratory review, was achieved in 99.1% of subjects who have been evaluated at 12 months post-procedure. The primary clinical success endpoint was achieved in 96.7% of subjects evaluated.

Frame Fractures
Within the Feasibility, Pivotal, and Continued Access Studies, fluoroscopy exams were conducted on device patients at both 6 and 12 months post-implant. Frame fractures were assessed during these exams, and noted as minor adverse events (as demonstrated in Table 3). No fractures of the wire frame were detected on either the 15 mm or 20 mm device. The incidence of frame fractures detected at the 6- and 12-month exams for the other devices were: 1.4% and 2.4% for the 25 mm device, 9.6% and 13.8% for the 30 mm device, and 16.7% and 22.9% for the 35 mm device, respectively. A detailed assessment of frame fractures observed in these studies is provided in a publication by Fagan et al. 2009.[1] Noteworthy in this assessment is the fact that 31.5% (6/19) of the observed frame fractures occurred in patients having an atrial septal aneurysm at the time of implant.
Although an association of frame fractures with serious adverse events is rare, clinical event reports have described events in which frame fractures have resulted in a second surgical or interventional procedure. For example, frame fractures have been observed in cases of residual shunts, excessive motion/improper apposition of the device, device displacement, separation of the right disc from the left disc, and mitral valve damage. The frequency of these events, based on voluntary reports, is estimated at < 0.1% of devices sold.
The mechanism for frame fractures is related to fatigue, and has been hypothesized as stemming from the repeated ovalization[2] of the device within the atrial chamber. No clinical sequelae were observed in these trials as a result of a wire frame fracture. Only one fracture was associated with device instability[3]. This device was removed surgically. The remaining fractures were detectable only by careful radiographic examination. No special treatment was recommended for incidentally detected asymptomatic fractures in stable devices.
It is recommended that patients should have TTE exams prior to discharge, and at 1, 6, and 12 months after occluder placement to assess, in addition to residual leak status, the stability of the device, as a lack of device stability may be indicative of wire frame fractures. In instances where device stability is questionable, fluoroscopic examination without contrast is recommended in order to identify and assess wire frame fractures. Routine fluoroscopic evaluation is not felt to be necessary in patients who are asymptomatic with stable devices by TTE.

[1] Fagan T, Dreher D, Cutright W, et al. Fracture of the GORE® HELEX Septal Occluder: associated factors and clinical outcomes. *Catheterization and Cardiovascular Interventions* 2009; 73(7):941-948.

[2] Device ovalization is defined as compression of the device with unequal force around the circumference leading to a slightly oval configuration instead of the intended circular configuration.

[3] Device instability is defined as abnormal motion of one portion of the device relative to the remaining portions of the device and the atrial septum.

Tables of Safety and Effectiveness Results
The principal safety and effectiveness results through 12 months and the procedure outcomes for the Pivotal and Continued Access Studies are reported in Tables 6 and 7.

TABLE 6: GORE® HELEX Septal Occluder Studies
Principal Safety and Effectiveness Results

	Pivotal Study			Continued Access Study
Study Outcomes	**Device Arm**	**Surgery Arm**	**Difference (95% CI)[4]**	
Technical Success[1]	119 / 135 (88.1%)	n/a	n/a	137 / 160 (85.6%)
Clinical Closure Success[2]				
Pre-discharge	115 / 118 (97.5%)	128 / 128 (100%)	-2.5% (-5.4%, 0.3%)	134 / 136 (98.5%)
Month 6	99 / 101 (98.0%)	n/a	n/a	111 / 111 (100%)
Month 12	103 / 105 (98.1%)	82 / 82 (100%)	-1.9% (-4.5%, 0.7%)	116 / 117 (99.1%)
Principal Safety Measures				
Major Adverse Events 12 Months	7 / 119 (5.9%)	14 / 128 (10.9%)	-5.1% (-11.9%, 1.8%)	3 / 137 (2.2%)
Minor Adverse Events 12 Months	34 / 119 (28.6%)	36 / 128 (28.1%)	0.4% (-10.8%, 11.7%)	46 / 137 (33.6%)
Survival at 365 Days (K-M)	100%	99.2%	-0.8% (-2.3% 0.7%)	100%
Composite Clinical Success 12 Months[3]	102/ 111 (91.9%)	73/ 87 (83.9%)	8.0% (-1.3%, 17.2%)	116 / 120 (96.7%)

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006 and evaluated through 12 month follow-up.
n/a - Not applicable
[1] Technical Success defined as successful delivery of the device in subjects with a delivery attempted
[2] Clinical Closure Success defined as residual defect that is either Completely Occluded or Clinically Insignificant Leak. Leak status was evaluated by the investigational sites at pre-discharge and six months and by the echocardiography core laboratory at 12 months
[3] Composite Clinical Success defined as no major adverse event or repeated procedure and clinical closure success at 12 months
[4] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

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TABLE 7: GORE® HELEX Septal Occluder Studies
Procedural Outcomes

	Pivotal Study			Continued Access Study
	Device Arm	Surgery Arm	Difference (95% CI)[1]	
Subjects with Delivery Attempt / Surgery	135	128		160
Total Time Under Fluoroscopy (minutes)				
n	134	n/a		155
Mean (Std Dev)	28 (21)			23 (16)
Median	22			19
Range	(6, 148)			(5, 116)
Total Time Under Anesthesia (minutes)				
n	133	128		155
Mean (Std Dev)	168 (63)	205 (43)	-37.1 (-50.3, -23.9)	153 (63)
Median	160	202		150
Range	(55, 360)	(30, 330)		(0, 380)
Days in Hospital for Procedure				
n	135	128		160
Mean (Std Dev)	1 (0)	3 (1)	-1.9 (-2.1, -1.7)	1 (0)
Median	1	3		1
Range	(0, 4)	(1, 9)		(0, 2)

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006.
n/a - Not applicable
[1] Differences between Pivotal device and surgery groups and associated 95% confidence intervals

Table 8 presents the number of devices attempted and number of those successfully delivered for each device size overall and by subject age at procedure for combined device subjects from the Pivotal and Continued Access Studies.

TABLE 8: GORE® HELEX Septal Occluder Studies
Number of Devices Attempted and Successfully Delivered
By Device Size and Subject Age at Procedure

	GORE® HELEX Device 15 mm (N_S/N_A)[1]	GORE® HELEX Device 20 mm (N_S/N_A)[1]	GORE® HELEX Device 25 mm (N_S/N_A)[1]	GORE® HELEX Device 30 mm (N_S/N_A)[1]	GORE® HELEX Device 35 mm (N_S/N_A)[1]	Overall (N_S/N_A)[1]
Subject Age						
Infant (< 2 yrs)	1 / 1	3 / 3	3 / 9	0	0	7 / 13
Child (2-5 yrs)	5 / 5	23 / 32	58 / 108	30 / 71	4 / 21	120 / 237
Child (6-11 yrs)	3 / 3	11 / 13	17 / 24	23 / 42	4 / 16	58 / 98
Adolescent (12-20 yrs)	2 / 2	8 / 11	13 / 18	11 / 16	13 / 24	47 / 71
Adult (21+ yrs)	0	1 / 1	5 / 5	7 / 8	11 / 18	24 / 32
Overall	11 / 11	46 / 60	96 / 164	71 / 137	32 / 79	256 / 451

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006.
[1] N_S = Number of successful device deliveries, N_A = number of devices attempted.

Table 9 presents the frequency of reported medications at follow-up visits for combined device subjects from the Pivotal and Continued Access Studies.

TABLE 9: GORE® HELEX Septal Occluder Studies
Summary of Reported Medications for Device Subjects

	Pre-Procedure	Pre-Discharge	Six Months	Twelve Months
Medications				
Anti-platelet	28 / 333 (8.4%)	224 / 255 (87.8%)	147 / 215 (68.4%)	21 / 236 (8.9%)
Anti-arrhythmic	7 / 333 (2.1%)	6 / 255 (2.4%)	5 / 215 (2.3%)	4 / 236 (1.7%)
Anti-hypertensive	6 / 333 (1.8%)	4 / 255 (1.6%)	3 / 215 (1.4%)	4 / 236 (1.7%)
Anti-coagulant	4 / 333 (1.2%)	13 / 255 (5.1%)	2 / 215 (0.9%)	4 / 236 (1.7%)
Diuretic	8 / 333 (2.4%)	2 / 255 (0.8%)	2 / 215 (0.9%)	2 / 236 (0.8%)

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006.

Table 10 presents a summary of procedural fluoroscopy time by device delivery success and number of devices attempted for combined device subjects from the Pivotal and Continued Access Studies.

TABLE 10: GORE® HELEX Septal Occluder Studies
Summary of Procedural Fluoroscopy Times for Device Subjects

	n	Median (minutes)	Range (minutes)
Subjects with Successful Delivery	**256**	**18.6**	**(5.3, 92.1)**
One Device Attempted	178	15.1	(5.3, 46.6)
Two Devices Attempted	54	28.9	(9.8, 76.1)
Three or More Devices Attempted	24	39.7	(24.0, 92.1)
Subjects with Unsuccessful Delivery	**39**	**36.0**	**(13.4, 148.0)**
One Device Attempted	19	26.3	(13.4, 51.3)
Two Devices Attempted	9	34.9	(31.3, 56.2)
Three or More Devices Attempted	11	74.2	(41.5, 148.0)

NOTE: Analysis includes all non-training Pivotal subjects and Continued Access subjects enrolled as of 08/01/2006.

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Conclusions
The clinical success outcomes satisfied the primary, non-inferiority hypothesis for the Pivotal Study ($p < 0.001$ using two-sample binomial proportions test with non-inferiority margin of 10%) and indicated that the clinical success rate of the GORE® HELEX Septal Occluder is not inferior to surgical closure.

HOW SUPPLIED
The GORE® HELEX Septal Occluder is supplied sterile in a protective tray in one or more pouches. Provided that the integrity of the pouches is not compromised in any way, they will serve as an effective barrier until the "use by" (expiration) date printed on the box.

REQUIRED ACCESSORIES
- Introducer Sheath, as recommended in Table 11
- Heparinized saline
- Large volume syringe (12-30 cc)
- Sizing balloon

OPTIONAL ACCESSORIES
Guidewire with diameter of 0.035" / 0.89 mm (if necessary for defect access)
Sterile bowl for flushing catheter
Stopcock

TABLE 11 : GORE® HELEX Septal Occluder Recommended Introducer Sheaths

Without Guidewire	With Guidewire
10 Fr or greater (I.D. ≥ 0.131 in. / 3.33 mm)	13 Fr or greater (I.D. ≥ 0.171 in. / 4.33 mm)
9 Fr TERUMO PINNACLE® Introducer Sheath[1]	12 Fr COOK CHECK-FLO® Introducer Sheath
	11 Fr TERUMO PINNACLE® Introducer Sheath

[1] Although this sheath is designed to accommodate catheters up to 9 Fr in diameter, internal testing has shown compatibility of this introducer sheath with the GORE® HELEX Septal Occluder catheter delivery system.

The use of introducer sheaths other than those specified in Table 11 is not recommended. For example, although Table 11 indicates that the use of the 12 Fr Cook Medical CHECK-FLO Introducer Sheath is acceptable when using a 0.035" guidewire, other 12 Fr introducer sheaths such as the 12 Fr St. Jude Medical FAST-CATH Guiding Introducer or the 12 Fr GORE ® Introducer Sheath are not recommended when using a 0.035" guidewire.

RECOMMENDED PROCEDURES

A. Sizing the Defect and Selecting the Proper Occluder Size

1. Use ultrasound to measure the septal length.
2. Measure the septal defect using a balloon technique, as described below:
   a. Place a contrast filled, compliant balloon across the defect and gently inflate until shunting through the defect has stopped.
   b. Measure the stretched diameter of the defect using either ultrasound or calibrated biplane fluoroscopy.
   c. Ensure there is adequate rim to retain the occluder in ≥ 75% of the circumference of the defect.
3. Identify and select the appropriate occluder size for the defect according to Table 12, taking the following into consideration:
   - **The occluder size selected for the defect should achieve at least a 2:1 ratio. Deploying the occluder in cases where the occluder diameter-to-defect diameter ratio is below 2:1 increases the risk of device embolization and residual defects. An occluder that pulls through the defect during disc conformation may be too small and should be removed and replaced with a larger size.**
   - The GORE® HELEX Septal Occluder is not recommended for defects larger than 18 mm.
   - To assure that there is adequate space to accommodate the disc within the atrial chambers, the selected occluder diameter should be no more than 90% of the measured septal length. Additionally, confirm that there is adequate space to accommodate the selected occluder size without impinging on adjacent cardiac structures (e.g., A-V valves, ostia of the pulmonary veins, coronary sinus).
   - The septal tissue margins surrounding the defect must be of sufficient size and integrity to prevent disc prolapse through the defect and embolization. The defect should be evaluated to ensure there is an adequate rim around its circumference to retain the device.

TABLE 12 : GORE® HELEX Septal Occluder Device Sizing

Labeled Occluder Diameter (mm)	Nominal Defect Size (mm)
15	7.5
20	10
25	12.5
30	15
35	17.5

B. Access Site Preparation

1. Throughout the procedure, the patient must be heparinized sufficiently to maintain an ACT greater than 200 seconds.
2. Prepare the venous access site according to standard practice.
3. Place appropriately sized Introducer Sheath (see Table 11).
   - **The use of introducer sheaths other than those specified in Table 11 is not recommended. For example, although Table 11 indicates that the use of the 12 Fr COOK® CHECK-FLO® Introducer Sheath is acceptable when using a 0.035" guidewire, other 12 Fr introducer sheaths such as the 12 Fr ST. JUDE FAST-CATH Guiding Introducer or the 12 Fr GORE® Introducer Sheath are not recommended when using a 0.035" guidewire.**

C. Occluder Preparation and Loading

1. Check the "use by" (expiration date) and the condition of the package. Inspect the product for damage and ensure that the eyelets are engaged over the mandrel.
2. Using aseptic technique, remove the sterile tray from the outer pouches. Remove the packaging tray lid and visually inspect the catheter and device for shipping damage.

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3. **Loading the occluder into the Green Delivery Catheter:**
   a. To reduce the chance of air entrapment in the delivery system, submerge the occluder and catheter tip in a heparinized saline bath during loading.
   b. Fill a large volume (12-30 cc) syringe with heparinized saline.
   c. Attach the syringe to the Red Retrieval Cord Cap. Alternatively, attach a stopcock to the Red Retrieval Cord Cap and subsequently attach the syringe. The use of the stopcock is at the physician's discretion, but may help prevent the backflow of air into the delivery system during the procedure.
   d. Tighten the Mandrel Luer.
   e. Loosen the Control Catheter Luer.
   f. Flush the Gray Control Catheter.
   g. When the initial flushing is completed, draw back on the Gray Control Catheter with the attached syringe until only about three centimeters of the occluder remain outside the Green Delivery Catheter and the Tan Mandrel appears slightly curved (see Figures 3 and 4).

FIGURE 3

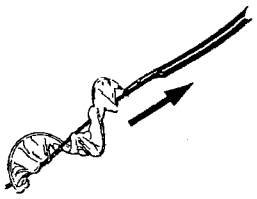
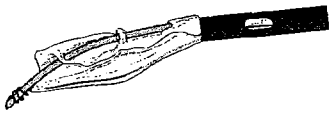


FIGURE 4

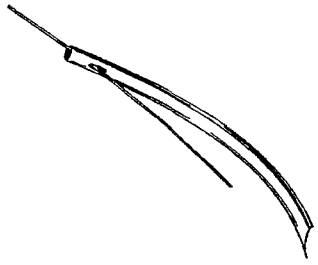


   h. Loosen the Mandrel Luer.
   i. Complete loading by continuing to draw back on the Gray Control Catheter until the entire occluder has been withdrawn into the Green Delivery Catheter. Care should be taken to prevent dislodging the Left Atrial Eyelet off the Tan Mandrel as it slides into the Green Delivery Catheter.
   j. If the occluder cannot be easily withdrawn into the Green Delivery Catheter, the product should not be used.
   k. Flush the Gray Control Catheter.
   l. Do not detach the flushing syringe from the Red Retrieval Cord Cap until the catheter tip is placed inside the introducer sheath to prevent the entrance of air into the delivery system.

D. Occluder Delivery

1. If applicable, ensure that the rotating hemostatic valve in the introducer sheath hub is sufficiently open prior to device insertion.
2. If applicable, load a 0.035" guidewire through the Guidewire Slot located at the distal end of the Green Delivery Catheter. Ensure that the occluder is sufficiently withdrawn into the Green Delivery Catheter to avoid interference with the guidewire. Load the Delivery Catheter onto a guidewire through the Guidewire Slot from the luminal surface out (see Figure 5).
3. Load the delivery system into the appropriately sized introducer sheath (Table 11). Remove the flushing syringe. Verify that the Red Retrieval Cord Cap affixing the Retrieval Cord is securely attached to the Gray Control Catheter.

FIGURE 5



E. Deployment

1. Under direct fluoroscopic visualization, advance the catheter tip across the atrial septal defect until the radiopaque marker at the tip of the Green Delivery Catheter is positioned within the left atrium. Verify that the tip of the Green Delivery Catheter is across the defect using TEE or ICE.
2. Remove the guidewire before attempting to deploy the occluder.
3. Use the following "push-pinch-pull" method to deploy the Left Atrial Occluder Disc:
   a. Push the Gray Control Catheter moving the occluder into the left atrial chamber off of the septum, but do not push against the atrial wall. If the chamber space is adequate, push until the Mandrel Luer stops against the Y-arm hub (approximately 2 cm).
   b. While holding the Green Delivery Catheter to maintain position, pinch the Gray Control Catheter.
   c. Pull the Tan Mandrel back approximately 2 cm or less to form exposed segment of occluder (Figure 6).
   d. Repeat the "push-pinch-pull" sequence until the center eyelet exits the Green Delivery Catheter tip demarcated by the radiopaque marker.

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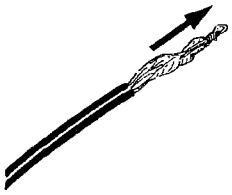
FIGURE 6



4. Once the Left Atrial Disc is deployed, gently retract the Tan Mandrel to flatten the Left Atrial Disc.
5. To prepare for Right Atrial Disc deployment, hold the Gray Control Catheter in a fixed position and gently expose a portion of the right atrial side by withdrawing the Green Delivery Catheter until the Mandrel Luer stops on the Y-arm hub (Figure 7).
6. Tighten the Mandrel Luer.
7. Deploy the Right Atrial Disc by holding the Green Delivery Catheter in a fixed position and pushing the Gray Control Catheter until the Control Catheter Luer contacts the Y-arm hub.
8. Tighten the Control Catheter Luer.
9. Confirm that both left and right discs appear planar and apposed to the septum with septal tissue between the discs (Figure 8).
10. **Confirm proper position using TEE or ICE. If the position is not correct, refer to Section G, "Reloading the Occluder". Note that the occluder can only be reloaded prior to lock release.**

FIGURE 7

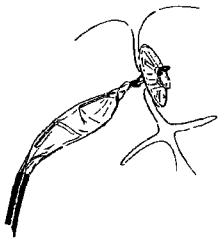


FIGURE 8

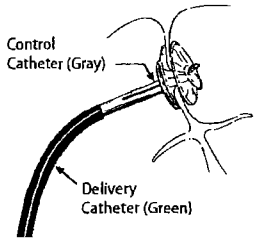


FIGURE 9

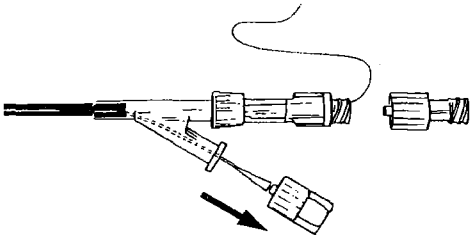
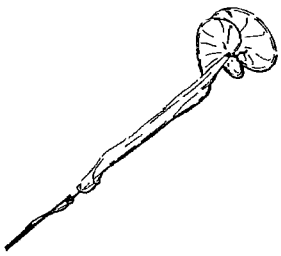


FIGURE 10



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F. Occluder Lock and Release

1. Remove the Red Retrieval Cord Cap and set it aside.
2. If position and occlusion are acceptable, loosen the Mandrel Luer. Hold the Green Delivery Catheter in a fixed position and release the lock by sharply pulling the Tan Mandrel at least 2 cm (Figure 9) while observing the lock by fluoroscopy. If a delay in lock release is experienced, slightly rotate the entire delivery system until the lock is released. Do not pull back on the delivery system, as this may result in a missed right atrial eyelet.
3. At the completion of the Lock and Release step, the occluder is still loosely attached to the Gray Control Catheter by the Retrieval Cord. If the occluder position is not acceptable, refer to **Section H, "Removing the Occluder with the Retrieval Cord"**. Once the delivery system is withdrawn, the occluder cannot be removed using the delivery system.
4. If position is acceptable, completely remove the Tan Mandrel from the Green Delivery Catheter while holding the Green Delivery Catheter in a fixed position.
5. While fixing the Gray Control Catheter, advance the Green Delivery Catheter to abut the right disc of the occluder.
6. Slowly remove the Gray Control Catheter from the Green Delivery Catheter making sure the retrieval cord moves smoothly through the Y-arm hub.
7. Remove the Green Delivery Catheter.

G. Reloading the Occluder

1. Ensure that the Red Retrieval Cord Cap is tightened.
2. If necessary, hold the Gray Control Catheter and pull back on the Green Delivery Catheter until the Mandrel Luer comes in contact with the Y-arm hub; tighten the Mandrel Luer.
3. Slowly draw back on the Gray Control Catheter until the desired portion of the occluder is reloaded. Note: If the entire occluder must be reloaded, continue to draw back on the Gray Control Catheter until the Tan Mandrel exhibits a slight bend (refer to **Section C, "Occluder Preparation and Loading"**). Loosen the Mandrel Luer and continue to draw back the Gray Control Catheter until the left atrial eyelet enters the Green Delivery Catheter.
4. Refer to **Section E, "Deployment"** to re-deploy the occluder.
   - **If increased force is required to move the catheter components due to abnormal conditions (such as a kinked mandrel or premature lock release), remove the occluder and delivery system entirely and utilize a new device.**
   - **If successful deployment cannot be achieved after two attempts, an alternative treatment for ASD closure should be considered. Consideration should be given to the patient's total exposure to radiation if prolonged or multiple attempts are required for the placement of the GORE® HELEX Septal Occluder.**

H. Removing the Occluder with the Retrieval Cord

1. Take up any slack in the Retrieval Cord and securely re-attach the Red Retrieval Cord Cap.
2. Withdraw the Gray Control Catheter to unlock the occluder, ensuring with fluoroscopy that the Green Delivery Catheter is sufficiently spaced away from the occluder to permit full extension of the locking loop (Figure 10).
3. Do not use excessive force in an attempt to withdraw all of the occluder into the Green Delivery Catheter. Doing so could cause the Retrieval Cord to break or result in occluder fracture.
   - **Without the Tan Mandrel to support the wire frame of the occluder, the operator must ensure that the lock loop and eyelets do not catch on the Green Delivery Catheter tip or introducer sheath. If the lock loop or eyelet catch and the delivery system is forcibly retracted, the retrieval cord or wire frame is at risk of fracture.**
4. If necessary, remove the introducer sheath and occluder together.
   - **If the occluder is removed, it should be disposed of and a new occluder should be used to complete the procedure.**

I. Recapture

1. In the event that the occluder is malpositioned, embolized, or otherwise requires removal, it may be recaptured with the aid of a loop snare or other suitable means. A long sheath (10 Fr or greater) positioned close to the device is recommended for recapture.
2. Place the loop snare around any portion of the occluder frame.
3. Pull the occluder into the sheath using the snare. If a portion of the occluder frame cannot be retracted into the long sheath, it may be necessary to remove the occluder, loop snare, and long sheath as one unit.
4. Bring the recaptured occluder into the sheath to avoid pulling the unlocked device across valve tissue.

J. Multiple Attempts to Close An Atrial Septal Defect

- If prolonged or multiple attempts at occluder placement are required, consideration should be given to minimize the patient's exposure to radiation (See Table 10). If the patient's septal anatomy is determined to be unsuitable for the GORE® HELEX Septal Occluder, alternative treatment options such as other occluder designs or surgical closure of the defect should be considered.
- If successful delivery cannot be achieved after two attempts, an alternate treatment for ASD closure should be considered.

K. Post-Procedural Recommendations

- Patients should take appropriate prophylactic antibiotic therapy consistent with the physician's routine procedures following device implantation.
- Patients should be treated with antiplatelet therapy, such as aspirin or clopidogrel bisulfate, for six months post-implant. The decision to continue antiplatelet therapy beyond six months is at the discretion of the physician.
- In patients sensitive to antiplatelet therapy, alternative therapies, such as anticoagulants, should be considered.
- Patients should be advised to avoid strenuous physical activity for a period of at least two weeks after occluder placement.
- Patients should have Transthoracic Echocardiographic (TTE) exams prior to discharge, and at 1, 6, and 12 months after occluder placement to assess defect closure. Attention should additionally be given towards the stability of the device during these assessments, as a lack of device stability may be indicative of wire frame fractures. In instances where device stability is questionable, fluoroscopic examination without contrast is recommended in order to identify and assess wire frame fractures.

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MR Conditional

L. MRI Information

The GORE HELEX Septal Occluder was determined to be MR-conditional.

Non-clinical testing has demonstrated that the GORE HELEX Septal Occluder is MR Conditional. A patient with this device can be scanned safely under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or 1.5 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss / cm or less
- Maximum scanner displayed whole-body averaged specific absorption rate (WB-SAR) of 3.0W/kg for 15 minutes of scanning

MRI-Related Heating

In non-clinical testing, the GORE HELEX Septal Occluder produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change: +1.6° C

Therefore, the MRI-related heating experiments for the GORE HELEX Septal Occluder at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 3.0-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.8-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6° C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE HELEX Septal Occluder. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

DEFINITIONS

Use By

Caution

Consult Instructions for Use

Do Not Resterilize

Do Not Reuse

REF Catalogue Number

LOT Batch Code

MR Conditional

℞ Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Do Not Use if Package is Damaged

Keep Dry

Store in a Cool Place

Diameter

Manufacturer

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Manufacturer
W. L. Gore & Associates, Inc.
Flagstaff, Arizona 86004 • USA
Order Information: Tel.: 928.526.3030 • Tel.: 800.528.8763
Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

DECEMBER 2010